

AMENDMENTS TO THE CLAIMS

The following is a complete listing of the claims indicating the current status of each claim and including amendments currently entered as highlighted.

1. (original) A drug delivery device for metered delivery of a liquid medicament to an outlet, the device comprising:

- (a) a pressurized reservoir configured for storing and supplying the liquid medicament at a pressure above atmospheric pressure;
- (b) a flow path in fluid communication with said pressurized reservoir and the outlet, said flow path including:
 - (i) a first valve assuming a normally-closed flow-blocking state and selectively actuatable to an open state which permits fluid flow through said first valve,
 - (ii) a flow restriction configured to limit fluid flow along said flow path, and
 - (iii) a second valve assuming a normally-closed flow-blocking state and selectively actuatable to an open state which permits fluid flow through said second valve,

such that, when both said first valve and second valve are in said open state, the liquid medicament flows from the pressurized reservoir along said flow path to the outlet at a rate limited primarily by said flow restriction;

- (c) a pressure measurement arrangement deployed in pressure-sensing engagement with a first point and a second point along said flow path, at least part of said flow restriction being between said first and second

points, one of said first and second points being intermediate to said first and second valves; and

- (d) a controller electronically associated with said pressure measurement arrangement and said first and second valves, and configured to selectively open said first and second valves to deliver a defined quantity of the liquid medicament to the outlet.

2. (original) The drug delivery device of claim 1, wherein said pressure measurement arrangement is configured to determine a differential pressure between fluid at said first and second points.

3. (original) The drug delivery device of claim 1, wherein said controller is configured to determine based upon a differential pressure between said first and second points a current flow rate of liquid medicament through said at least part of said flow restriction.

4. (original) The drug delivery device of claim 1, wherein said controller is configured to actuate pulsed opening of said first and second valves between said normally-closed state and said open state.

5. (original) The drug delivery device of claim 1, wherein said controller is configured to:

- (a) actuate both said first and second valves to assume said open state;
- (b) compare a differential pressure between said first and second points to a minimum expected differential pressure value; and

- (c) if said differential pressure is less than said minimum expected differential pressure value, generate a malfunction indication.

6. (original) The drug delivery device of claim 1, wherein said controller is configured to:

- (a) actuate said first and second valves such that said first and second valves close sequentially, thereby trapping a quantity of the liquid medicament between said first and second valves with a pressure differential across said first valve;
- (b) while said first and second valves are closed, monitor measurements of said pressure measurement arrangement; and
- (c) if said measurements vary so as to indicate a reduction in said pressure differential across said first valve, generate a malfunction indication.

7. (original) The drug delivery device of claim 1, wherein said controller is configured to:

- (a) actuate said first and second valves such that said first and second valves close sequentially, thereby trapping a quantity of the liquid medicament between said first and second valves with a pressure differential across said second valve;
- (b) while said first and second valves are closed, monitor measurements of said pressure measurement arrangement; and
- (c) if said measurements vary so as to indicate a reduction in said pressure differential across said second valve, generate a malfunction indication.

8. (original) The drug delivery device of claim 1, wherein said pressurized reservoir includes an elastic pressurizing member such that a fluid pressure within said reservoir varies as a function of a volume of the liquid medicament currently stored, and wherein said controller is configured to:

- (a) estimate a remaining volume of the liquid medicament in said reservoir based upon at least one measurement from said pressure measurement arrangement obtained under zero flow conditions; and
- (b) if said remaining volume is less than a minimum volume value, generate a low-remaining-volume indication.

9. (original) The drug delivery device of claim 1, wherein said controller is configured to:

- (a) during operation of the drug delivery device, repeatedly:
 - (i) selectively actuate one of said first and second valves to said open state such that said pressure measurement arrangement measures a value of a differential fluid pressure under zero flow conditions between said reservoir and the outlet, and
 - (ii) store said differential fluid pressure values;
- (b) monitor said stored values to identify an increase in said values relative to a mean peak pressure difference; and
- (c) if an increase in said values is identified, generate a disconnection indication.

10. (original) The drug delivery device of claim 1, wherein said pressurized reservoir is configured to deliver the liquid medicament at a pressure in excess of four atmospheres.

11. (original) The drug delivery device of claim 1, further comprising a reservoir pressure release mechanism associated with said controller and selectively actuatable to depressurize said reservoir so as to deactivate delivery of the liquid medicament to the outlet.

12. (original) The drug delivery device of claim 1, wherein the device includes a body and a removable cartridge, wherein said pressurized reservoir and said flow path are implemented as part of said removable cartridge, and wherein said controller is implemented as part of said body.

13. (original) The drug delivery device of claim 12, wherein said first and second valves are implemented as part of said replaceable cartridge, each of said valves having an actuator surface isolated from said fluid flow path, said valve being configured such that force applied to said actuator surface actuates said valve to assume said open state, and wherein said body includes at least one electrically operated actuator deployed for selectively applying a force to at least one of said actuator surfaces.

14. (original) The drug delivery device of claim 13, wherein said actuator includes:

- (a) at least one piezoelectric element electrically actuatable to generate a first displacement; and
- (b) a mechanical amplifier mechanically cooperating with said piezoelectric element such that said first displacement of said piezoelectric element generates a second displacement of said actuator

surface, said second displacement being greater than said first displacement.

15. (original) The drug delivery device of claim 12, wherein said pressure measurement arrangement includes a differential pressure sensor mounted included within said body, said differential pressure sensor being in fluid connection with two connectors, and wherein said removable cartridge includes a pair of pressure sensing cells each separated from said flow path by a flexible membrane and each having a complementary connector, such that, when said removable cartridge is engaged with said body, each of said sensor connectors mates with a corresponding complementary connector such that said differential pressure sensor measures a differential pressure between liquid in said flow path at said first and second points.

16. (original) A drug delivery device for metered delivery of a liquid medicament to an outlet, the device comprising:

- (a) a pressurized reservoir configured for storing and supplying the liquid medicament at a pressure above atmospheric pressure;
- (b) a flow path in fluid communication with said pressurized reservoir and the outlet, said flow path including:
 - (i) a first valve assuming a normally-closed flow-blocking state and selectively adjustable to provide a flow restriction configured to limit fluid flow along said flow path, and
 - (ii) a second valve assuming a normally-closed flow-blocking state and selectively actuatable to an open state which permits fluid flow through said second valve,

such that, when both said first valve and second valve are both opened, the liquid medicament flows from the pressurized reservoir along said flow path to the outlet at a rate limited primarily by said flow restriction of said first valve;

- (c) a pressure measurement arrangement deployed in pressure-sensing engagement with a first point and a second point along said flow path, said first valve being between said first and second points, said second point being intermediate to said first and second valves; and
- (d) a controller electronically associated with said pressure measurement arrangement and said first and second valves, and configured to selectively actuate said first and second valves to deliver a defined quantity of the liquid medicament to the outlet.

17. (currently amended) In a drug delivery device having a pressurized source of a liquid medicament supplying a flow path including two valves and a flow restriction, a method for identifying malfunction of at least one of the valves, the method comprising:

- (a) closing both valves in such a manner as to ensure a pressure differential across at least one of the valves; and
- (b) monitoring for a change in liquid pressure between the valves,

wherein said closing is performed in such a manner as to ensure a pressure differential across both of the valves, such that an increase in pressure between the two valves indicates leakage of a first of the valves and a decrease in pressure between the two valves indicates leakage of a second of the valves.

18. (canceled)

19. (original) The method of claim 17, wherein said monitoring includes measuring a pressure differential between said pressurized source and liquid between the valves.

20. (original) A method for delivery of a liquid medicament to an outlet, the method comprising:

- (a) providing a drug delivery device including:
 - (i) a pressurized reservoir storing and supplying the liquid medicament at a pressure above atmospheric pressure;
 - (ii) a flow path in fluid communication with said pressurized reservoir and the outlet, said flow path including two valves and a flow restriction;
- (b) opening the two valves to allow flow from the reservoir through the flow restriction to the outlet;
- (c) while the drug is flowing, measuring a fluid pressure differential across at least part of the flow restriction and deriving from the pressure differential a rate of fluid flow;
- (d) closing at least one of the valves; and
- (e) monitoring a differential fluid pressure between two points in the flow path while at least one of the valves is closed so as to identify at least one state of malfunction.

21. (original) The method of claim 20, wherein said opening is implemented as pulsed opening of the two valves between a normally-closed state and an open state.

22. (original) A fluid drug delivery device comprising:

- (a) a cartridge including a fluid supply assembly, a fluid outlet, and a flow control arrangement including a flow control valve, said flow control arrangement controlling flow from said fluid supply assembly to said fluid outlet, said flow control valve being operated by displacement of at least one actuation surface provided by said cartridge, said actuation surface being isolated from contact with the fluid;
- (b) a portable base unit configured for receiving said cartridge in removable engagement with said base unit, said base unit including:
 - (i) a processing unit,
 - (ii) a piezoelectric actuator controlled by said processing unit, and
 - (iii) a mechanical amplifier associated with said piezoelectric actuator and configured to produce an output displacement at an output surface, said output displacement having an amplitude greater than an output displacement of said piezoelectric actuator; and
- (c) an adjustment mechanism associated with one of said cartridge and said base unit, said adjustment mechanism being operative, after engagement of said cartridge with said base, to bring said output surface of said mechanical amplifier into contact with said actuation surface.

23. (original) The device of claim 22, wherein said adjustment mechanism includes a spring element disposed to bias said mechanical amplifier to move such that said output surface comes into contact with said actuation surface and

a clamping mechanism selectively operable to fix a current position of said mechanical amplifier.

24. (original) The device of claim 23, wherein said cartridge includes a second flow control valve, and wherein said portable base unit includes a second piezoelectric actuator and a second mechanical amplifier, said adjustment mechanism including a second spring element for biasing said second mechanical amplifier into operative relation to said second flow control valve, wherein said clamping mechanism is configured to simultaneously fix a current position of both of said mechanical amplifiers.

25-29. (canceled)

30. (original) A fluid drug delivery device comprising:
- (a) a pressurized fluid reservoir configured for storing and supplying the fluid drug at a pressure above atmospheric pressure;
 - (b) a flow regulating system associated with said fluid reservoir and configured to control flow from said fluid reservoir to a fluid outlet, said flow regulating system including a controller operative to detect at least one predefined malfunction condition; and
 - (c) a reservoir pressure release mechanism associated with said controller so as to be actuated in response to said malfunction condition to depressurize said reservoir, thereby interrupting flow from said fluid reservoir to said outlet.

31. (original) The device of claim 30, wherein said reservoir includes a cavity initially having a cavity pressure below atmospheric pressure, said pressure release mechanism being operative to release at least a portion of the fluid drug into said cavity so as to depressurize the fluid without release of fluid outside said reservoir.

32. (original) The device of claim 31, wherein the fluid in said reservoir is pressurized by at least one spring, said spring being located at least partially within said cavity.